

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

DUFT et al

Appl. No.: **08/870,762**

Filed: **June 6, 1997**

For: **Methods For Treating Obesity**

Confirmation No.: **7328**

Art Unit: **1645**

Examiner: **Sarvamangala J.N. DEVI**

Atty. Docket: **226/104 US**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Reply Brief under 37 CFR §41.41

In response to the **Examiner's Answer** mailed October 29, 2008, Appellants are submitting this Reply Brief which is due on or before December 29, 2008.

No fees are believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 010535 referencing Atty. Dkt. No. 226/104 US to maintain the pendency of this application.

Status of Claims begins on Page 2.

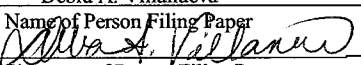
Grounds of Rejection to be Reviewed on Appeal begins on Page 3.

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CERTIFICATE OF TRANSMITTAL UNDER 37 C.F.R. 1.8

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being electronically filed via EFS-Web at the United States Patent and Trademark Office, on the date shown below.

December 11, 2008
Date of Deposit

Debra A. Villanueva
Name of Person Filing Paper

Signature of Person Filing Paper

Status of Claims

Claims 1-7 and 9-17 are pending and under appeal. Claim 8 was previously canceled.

Grounds of Rejection to be Reviewed on Appeal

1. Whether claims 7, 14, 16, and 17 are unpatentable under the judicially-created doctrine of obviousness-type double patenting over claims 34 and 35 of Gaeta, U.S. Patent No. 5,686,411, (hereinafter "Gaeta") as evidenced by Tsanev, *Vutr. Boles*, 23:12-17 (1984) (hereinafter "Tsanev").

2. Whether claims 7, 14, and 16 are unpatentable under the judicially-created doctrine of obviousness-type double patenting over claims 11 and 13 of Beaumont, U.S. Patent No. 5,321,008, (hereinafter "Beaumont") as evidenced by Tsanev, *Vutr. Boles*, 23:12-17 (1984) (hereinafter "Tsanev").

3. Whether claims 1, 7, 14, and 16, and claims 2-6, 9-13, 15 and 17, lack an adequate written description under 35 U.S.C. § 112, First Paragraph, as containing new matter.

4. Whether claims 1-7 and 9-17 lack enablement under 35 U.S.C. § 112, First Paragraph.

5. Whether claims 1-7, 9-14, 16 and 17 are anticipated under 35 U.S.C. § 102(a) by Kolterman, WO 96/40220, (hereinafter "Kolterman '220") as evidenced by Tsanev, *Vutr. Boles*, 23:12-17 (1984) (hereinafter "Tsanev").

6. Whether claims 7, 14 and 16 are anticipated under 35 U.S.C. § 102(e)(2) by Beaumont, U.S. Patent No. 5,321,008, (hereinafter "Beaumont") as evidenced by Tsanev, *Vutr. Boles*, 23:12-17 (1984) (hereinafter "Tsanev").

7. Whether claims 7, 14, 16 and 17 are anticipated under 35 U.S.C. § 102(e)(2) by Gaeta, U.S. Patent No. 5,686,411, (hereinafter "Gaeta") as evidenced by Tsanev, *Vutr. Boles*, 23:12-17 (1984) (hereinafter "Tsanev").

8. Whether claims 1-7, 9, 11-14, 16 and 17 are anticipated under 35 U.S.C. § 102(b) by Kolterman et al, *Diabetologia*, 39:492-499 (April 1996) (hereinafter "Kolterman 1996") as evidenced by Itasaka et al, *Psychiatr. Clin. Neurosci.*, 54:340-341 (June 2000) (hereinafter "Itasaka").

Arguments

1. Claims 7, 14, 16 and 17 are not obvious under the judicially-created doctrine of obviousness-type double patenting over Gaeta as evidenced by Tsanev.

Appellants incorporate herein the Arguments presented in the Brief on Appeal filed 7 August 2008.

Gaeta is directed to methods of treating diabetes. The word “obesity” does not appear in Gaeta. Gaeta (1) never contemplated or considered treating obesity, (2) never conducted any experiments for treating obesity, (3) never analyzed any results on the treatment of obesity; and (4) never presented any findings on the treatment of obesity. Gaeta had no intention to treat obesity.

Gaeta does not disclose, teach or suggest the limitations in the pending claims that recite, *inter alia*:

- “A method of treating obesity...”
- “...an amount effective to inhibit weight gain or induce weight loss...”
- “...wherein said subject is in need of treatment for obesity.”

Tsanev is irrelevant to the claimed invention because it does not cure the deficiencies of Gaeta. Assuming, *arguendo*, that Tsanev is relevant it does not provide evidence of inherent anticipation by Gaeta.

The **Examiner’s Answer** incorrectly applies the law on inherent anticipation. A claimed invention is inherent in the prior art if it is a “necessary and inevitable” consequence of the disclosure in a prior art reference. *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1378-1380 (Fed. Cir. 2003) (Emphasis Added). Stated another way, “[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Continental Can Company USA v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (Emphasis Added).

The **Examiner’s Answer** proves that Gaeta cannot anticipate the claimed invention. Tsanev teaches that at least 10-20% of diabetic patients are NOT obese. If at least 10-20% of diabetic patients are NOT obese, then the treatment of obesity is not a necessary and inevitable

consequence of Gaeta's treatment of diabetes. That a treatment for obesity may result (which is not guaranteed because at least 10-20% of diabetics are NOT obese) is not sufficient to establish inherency.

To summarize, in order for a prior art reference to inherently anticipate, the same result (e.g., treatment for obesity) must occur in the prior art reference each and every time (i.e., inevitable). Because at least 10-20% of diabetic patients are not obese, a treatment for obesity cannot occur each and every time by practicing Gaeta.

Appellants request that the Board of Patent Appeals and Interferences remand this case to the Examiner with instructions to withdraw this rejection of Claims 7, 14, 16, and 17 under the judicially created doctrine of obviousness-type double patenting.

2. Claims 7, 14 and 16 are not obvious under the judicially created doctrine of obviousness-type double patenting over Beaumont as evidenced by Tsanev.

Rink (US Patent No. 5,739,106) has been withdrawn from this rejection in the **Examiner's Answer** at Page 2, Part 6(ii).

Appellants incorporate herein the Arguments presented in the Brief on Appeal filed 7 August 2008.

Beaumont is directed to methods of treating diabetes. The word "obesity" does not appear in Beaumont. Beaumont (1) never contemplated or considered treating obesity, (2) never conducted any experiments for treating obesity, (3) never analyzed any results on the treatment of obesity; and (4) never presented any findings on the treatment of obesity. Beaumont had no intention to treat obesity.

Beaumont does not disclose, teach or suggest the limitations in the pending claims that recite, *inter alia*:

- "A method of treating obesity..."
- "...an amount effective to inhibit weight gain or induce weight loss..."
- "...wherein said subject is in need of treatment for obesity."

Tsanev is irrelevant to the claimed invention because it does not cure the deficiencies of Beaumont. Assuming, *arguendo*, that Tsanev is relevant it does not provide evidence of inherent anticipation by Beaumont.

The **Examiner's Answer** incorrectly applies the law on inherent anticipation. A claimed invention is inherent in the prior art if it is a "necessary and inevitable" consequence of the disclosure in a prior art reference. *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1378-1380 (Fed. Cir. 2003) (Emphasis Added). Stated another way, "[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can Company USA v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (Emphasis Added).

The **Examiner's Answer** proves that Beaumont cannot anticipate the claimed invention. Tsanev teaches that at least 10-20% of diabetic patients are NOT obese. If at least 10-20% of diabetic patients are NOT obese, then the treatment of obesity is not a necessary and inevitable consequence of Beaumont's treatment of diabetes. That a treatment for obesity may result (which is not guaranteed because at least 10-20% of diabetics are NOT obese) is not sufficient to establish inherency.

To summarize, in order for a prior art reference to inherently anticipate, the same result (e.g., treatment for obesity) must occur in the prior art reference each and every time (i.e., inevitable). Because at least 10-20% of diabetic patients are not obese, a treatment for obesity cannot occur each and every time by practicing Beaumont.

Appellants request that the Board of Patent Appeals and Interferences remand this case to the Examiner with instructions to withdraw this rejection of Claims 7, 14 and 16 under the judicially created doctrine of obviousness-type double patenting.

3. Claims 1, 7, 14 and 16, and the claims dependent thereon, satisfy the Written Description Requirement under 35 U.S.C. § 112, First Paragraph, because they do not contain new matter.

Appellants incorporate herein the Arguments presented in the Brief on Appeal filed 7 August 2008.

The **Examiner's Answer** appears to be requiring Appellants' specification to describe the claimed invention in *ipsis verbis*. This is not the standard. According to the Board of Patent Appeals and Interferences in *Ex parte Sorenson*, 3 U.S.P.Q.2d 1462, 1463 (P.T.O. Bd. Pat. App.

& Int'f 1987), the test for determining whether a claimed invention is adequately described in the specification is whether the originally filed disclosure *reasonably* conveys to a person having ordinary skill in the art that the Appellants had possession of the subject matter later claimed.

When viewed as a whole, Appellants' claimed invention is adequately described in the specification to reasonably convey to a person skilled in the art that Appellants were in possession of the claimed subject, e.g., for the reasons discussed in the Brief on Appeal filed 7 August 2008, the contents of which are incorporated herein by reference.

Appellants request that the Board of Patent Appeals and Interferences remand this case to the Examiner with instructions to withdraw this rejection of Claims 1, 7, 14, and 16 under 35 U.S.C. § 112, first paragraph.

4. Claims 1-7 and 9-17 are Enabled under 35 U.S.C. § 112, First Paragraph.

Appellants incorporate herein the Arguments presented in the Brief on Appeal filed 7 August 2008.

The **Examiner's Answer** (e.g., at page 6) appears to state that the only claim that would be enabled would be a claim that exactly duplicates all the conditions in Example 1. Appellants' specification when viewed as a whole, including Example 1, provides guidance for the skilled artisan to practice the claimed invention without undue experimentation for the reasons discussed in the Brief on Appeal filed 7 August 2008, the contents of which are incorporated herein by reference.

Appellants request that the Board of Patent Appeals and Interferences remand this case to the Examiner with instructions to withdraw this rejection of Claims 1-7 and 9-17 under 35 U.S.C. § 112, first paragraph.

5. Claims 1-7, 9-14, 16 and 17 are not anticipated under 35 U.S.C. § 102(a) by Kolterman '220 as evidenced by Tsanev.

Appellants incorporate herein the Arguments presented in the Brief on Appeal filed 7 August 2008.

Kolterman '220 is directed to methods of treating diabetes. Kolterman '220 (1) never contemplated or considered treating obesity with amylin or amylin agonists, (2) never conducted

any experiments with amylin or amylin agonists for treating obesity, (3) never analyzed any results on the treatment of obesity with amylin or amylin agonists; and (4) never presented any findings on the treatment of obesity with amylin or amylin agonists. Kolterman 1996 had no intention to treat obesity.

Kolterman '220 does refer to obesity and weight; however, the **Examiner's Answer** mischaracterizes Kolterman '220. In the Background of the Invention, Kolterman '220 provides the following references to obesity/weight:

The hyperglycemia associated with Type II diabetes can sometimes be reversed or ameliorated by diet or weight loss sufficient to restore the sensitivity of the peripheral tissues to insulin. Kolterman '220 at page 7, lines 9-12.

Lifestyle modifications include the maintenance of regular exercise, as an aid both to weight control and also to reduce the degree of insulin resistance. Kolterman '220 at page 8, lines 20-22.

Type II diabetics who fail to respond to diet and weight loss may respond to therapy with oral hypoglycemic agents such as sulfonylureas and biguanides. Insulin therapy, however, is used to treat other patients with Type II diabetes, especially those who have undergone primary dietary failure and are not obese.... Kolterman '220 at page 8, lines 29-36.

Nothing in the Background of the Invention of Kolterman '220 provides any motivation or suggestion to use amylin or amylin agonists to treat obesity. Nothing in these statements suggest that Kolterman '220 had any intention to treat obesity with amylin or amylin agonists.

In the Summary of the Invention at page 10, lines 6-15, Kolterman '220 provides the following reference to weight/obesity:

In one aspect, the present invention is directed to a method for the treatment of a non-insulin-taking Type II diabetic subject comprising administering a therapeutically effective amount of an amylin agonist. By "non-insulin-taking" Type II diabetic subject" is meant a subject who has Type II diabetes mellitus, but whose diabetes is currently being managed without the use of insulin, for example, by any combination of diet, exercise, lifestyle modification, or use of oral hypoglycemic agents, such as biguanides and sulfonylureas.

Again, nothing in this part of Kolterman '220 provides any motivation or suggestion to use amylin or amylin agonists to treat obesity. Nothing in these statements suggest that Kolterman

‘220 had any intention to treat obesity with amylin or amylin agonists.

Kolterman ‘220 simply does not disclose, teach or suggest the limitations in the pending claims that recite, *inter alia*:

- “A method of treating obesity...”
- “...an amount effective to inhibit weight gain or induce weight loss...”
- “...wherein said subject is in need of treatment for obesity.”

The **Examiner’s Answer** incorrectly applies the law on inherent anticipation. A claimed invention is inherent in the prior art if it is a “necessary and inevitable” consequence of the disclosure in a prior art reference. *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1378-1380 (Fed. Cir. 2003) (Emphasis Added). Stated another way, “[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Continental Can Company USA v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (Emphasis Added).

The **Examiner’s Answer** proves that Kolterman ‘220 cannot anticipate the claimed invention. Tsanev teaches that at least 10-20% of diabetic patients are NOT obese. If at least 10-20% of diabetic patients are NOT obese, then the treatment of obesity is not a necessary and inevitable consequence of Kolterman ‘220’s treatment of diabetes. That a treatment for obesity may result (which is not guaranteed because at least 10-20% of diabetics are NOT obese) is not sufficient to establish inherency.

To summarize, in order for a prior art reference to inherently anticipate, the same result (e.g., treatment for obesity) must occur in the prior art reference each and every time (i.e., inevitable). Because at least 10-20% of diabetic patients are not obese, a treatment for obesity cannot occur each and every time by practicing Kolterman ‘220.

Appellants request that the Board of Patent Appeals and Interferences remand this case to the Examiner with instructions to withdraw this rejection of Claims 1-7, 9-14, 16, and 17 under 35 U.S.C. § 102(a).

6. Claims 7, 14 and 16 are not anticipated under 35 U.S.C. § 102(e)(2) over Beaumont as evidenced by Tsanev.

Appellants incorporate herein (i) the Arguments presented in this Reply Brief in Part 2, above, because the arguments for the obviousness-type double patenting rejection also apply to the Arguments for this anticipation rejection; and (ii) the Arguments presented in the Brief on Appeal filed 7 August 2008. Appellants request that the Board of Patent Appeals and Interferences remand this case to the Examiner with instructions to withdraw this rejection of Claims 7, 14 and 16 under 35 U.S.C. § 102(e)(2).

7. Claims 7, 14, 16 and 17 are not anticipated under 35 U.S.C. § 102(e)(2) over Gaeta as evidenced by Tsanev.

Appellants incorporate herein (i) the Arguments presented in this Reply Brief in Part 1, above, because the arguments for the obviousness-type double patenting rejection also apply to the Arguments for this anticipation rejection; and (ii) the Arguments presented in the Brief on Appeal filed 7 August 2008.

Appellants request that the Board of Patent Appeals and Interferences remand this case to the Examiner with instructions to withdraw this rejection of Claims 7, 14, 16 and 17 under 35 U.S.C. § 102(e)(2).

8. Claims 1-7, 11-14, 16 and 17 are not anticipated under 35 U.S.C. § 102(b) over Kolterman 1996 as evidenced by Itasaka.

Appellants incorporate herein the Arguments presented in the Brief on Appeal filed 7 August 2008.

Kolterman 1996 is directed to methods of treating diabetes. Kolterman 1996 (1) never contemplated or considered treating obesity, (2) never conducted any experiments for treating obesity, (3) never analyzed any results on the treatment of obesity; and (4) never presented any findings on the treatment of obesity. Kolterman 1996 had no intention to treat obesity.

Kolterman 1996 states that the subjects had a body mass index (BMI) of less than 27 (*see* page 493, left column). Thus, Kolterman 1996 teaches that at least some patients were

overweight. However, there is no evidence that all of the patients were overweight.¹ Contrary to the statements made in the **Examiner's Answer** at page 17, line 28, there is absolutely no evidence that a subject weighing 70 kilograms or more is overweight or obese. Knowing a subject's weight, without knowing their height, does not support any assertion that the subject is overweight. For example, 70 kilograms is only 154 pounds.² No evidence exists to support the notion that each and every person weighing 154 pounds is overweight or obese.

Kolterman 1996 simply does not disclose, teach or suggest the limitations in the pending claims that recite, *inter alia*:

- "A method of treating obesity..."
- "...an amount effective to inhibit weight gain or induce weight loss..."
- "...wherein said subject is in need of treatment for obesity."

The **Examiner's Answer** incorrectly applies the law on inherent anticipation. A claimed invention is inherent in the prior art if it is a "necessary and inevitable" consequence of the disclosure in a prior art reference. *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1378-1380 (Fed. Cir. 2003) (Emphasis Added). Stated another way, "[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can Company USA v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (Emphasis Added).

The **Examiner's Answer** proves that Kolterman 1996 cannot anticipate the claimed invention. Kolterman 1996 teaches that the subjects had a BMI of less than 27; however, there is no evidence that all of the subjects were overweight or obese.³ Because at least some of the diabetic patients in Kolterman 1996 are NOT obese, the treatment of obesity is not a necessary

¹ The Centers for Disease Control states, *inter alia*, that a BMI of 25 to 29 is overweight, and that a BMI of 18.5 to 24.9 is normal. See <http://www.cdc.gov/nccdphp/dnpa/healthyweight/assessing/index.htm>. The weight of the patient (e.g., shown in Table 1) is irrelevant to the analysis because weight alone does not indicate whether a patient is overweight or obese. Obesity is determined based on the weight of a patient in view of their height. For example, 174.5 kilograms in Table 1 converts to 164.2 pounds. Without knowing the height of the subject, it is impossible to determine if the subject weighing 164.2 pounds is overweight or obese.

² It is known that 1 kilogram = 2.20462262 pounds.

³ It appears that the Examiner is in agreement with this fact. See Examiner's Answer at page 17, lines 17-18.

and inevitable consequence of Kolterman 1996's treatment of diabetes. That a treatment for obesity may result (which is not guaranteed because all the subjects in Kolterman 1996 were not obese) is not sufficient to establish inherency.

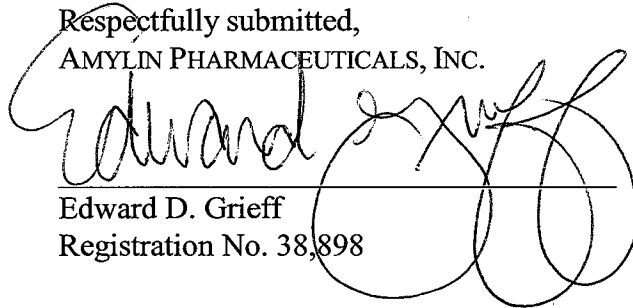
To summarize, in order for a prior art reference to inherently anticipate, the same result (e.g., treatment for obesity) must occur in the prior art reference each and every time (i.e., inevitable). Because there is no evidence that all the diabetic patients in Kolterman 1996 were overweight or obese, a treatment for obesity cannot occur each and every time by practicing Kolterman 1996.

Appellants request that the Board of Patent Appeals and Interferences remand this case to the Examiner with instructions to withdraw this rejection of Claims 1-7, 11-14, 16 and 17 under 35 U.S.C. § 102(b).

9. Conclusion

In view of the foregoing, Appellants request that the Board of Patent Appeals and Interferences remand the application to the Examiner with instructions to withdraw the outstanding rejections and issue a Notice of Allowance for all the pending claims.

Respectfully submitted,
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Date: December 11, 2008
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